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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/602,663

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Pierre Charneau

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EXAMINER

HUMPHREY, LOUISE WANG ZHIYING

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/602,663	Applicant(s) CHARNEAU ET AL.	
	Examiner LOUISE HUMPHREY	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-46, 50, 51, 66-73 and 78-93 is/are pending in the application.
- 4a) Of the above claim(s) 86-89 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-46, 50, 51, 66-85 and 90-93 is/are rejected.
- 7) ☒ Claim(s) 43, 45, 78 and 90 is/are objected to.
- 8) ☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 December 2008 has been entered.

DETAILED ACTION

This Office Action is in response to the amendment filed 23 December 2008. Claims 1-40, 47-49, 52-65 and 74-77 have been cancelled. Claims 78-93 have been added. Claims 41-46, 50, 51, 66-73 and 78-93 are pending. New claims 86-89 are drawn to a nonelected subject matter and hence are withdrawn from further consideration pursuant to 37 CFR 1.142(b). Claims 41-46, 50, 51, 66-85 and 90-93 are currently examined.

Claim Objections

Claim 43, 45, 78 and 90 are object to because of the following informalities:

Claims 43 and 45 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. The recitation "the

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polynucleotide comprising the cPPT and CTS regions are derived from an HIV-type retrovirus" in claim 43 and the recitation "the cis-acting central initiation region (cPPT) and the termination region (CTS) of an HIV-1 retroviral genome" in claim 45 do not further limit the phrase "wherein the cPPT and CTS are derived from a retrotransposon" in the base claim 41.

Claim 78 is objected to for the typographical error in line 2 in the phrase "inside a protein envelope of the non-infectious practice." Applicants may consider changing the word "practice" to "particle."

Claim 90 recites "POL," GAG" and "ENV" polypeptides. The art-recognized nomenclature for a protein is the capitalized initial letter followed by non-capitalized two letters, for example, Pol, Env, Pro and Gag. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41-45, 51, 66-70, 73, 78-85 and 90-93 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 36, 39, 41, 43-45, 52 and 69-73 of copending Application No. 10/313,038.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are anticipated by the copending claims.

Although there are different wordings, both sets of claims recite the same structural limitations. Therefore, the copending claims fall entirely within the scope of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 62-65 and 74-77 under 35 U.S.C. §112, second paragraph, as being indefinite is withdrawn in response to the Applicants' cancellation of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 41-46, 50, 51 and 66-73 under 35 U.S.C. §103(a) as being obvious over Verma *et al.* (WO 97/12622, hereinafter "Verma") in view of Charneau *et al.* (1994, hereinafter "Charneau'94") and Charneau *et al.* (1992, hereinafter "Charneau'92") is **withdrawn** in view of Applicant's arguments.

Response to Arguments

Applicant's arguments with respect to claims 41-46, 50, 51 and 66-73 have been considered but are moot in view of the new ground of rejection.

New Ground of Rejection

Claims 41-46, 50, 51, 66-73, 78-85 and 90-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verma *et al.* (WO 97/12622, hereinafter "Verma") in view of Charneau *et al.* (1994, hereinafter "Charneau'94"), Charneau *et al.* (1992, hereinafter "Charneau'92") and Giovannangeli *et al.* (1997, hereinafter "Giovannangeli").

Claims 41-46, 50, 51, 66-73, 78-85 and 90-93 are directed to a recombinant, non-replicative, non-infectious, lentiviral transfer vector deprived of functional genes

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encoding lentiviral Gag, Pol, and Env proteins, comprising: (1) a polynucleotide comprising a cis-acting central polypurine tract ("cPPT") and central terminator sequence ("CTS"), wherein the cPPT and CTS are of the central polypurine tract ("cPPT") retroviral-like origin and derived from a retrotransposon and which form a triple-stranded sequence (DNA triplex); (2) a defined nucleotide sequence (transgene or sequence of interest); and (3) regulatory signals for reverse transcription, expression, and packaging, wherein said regulatory signals are of retroviral or retroviral-like origin; and wherein the DNA triplex transfers the defined nucleotide sequence into the nucleus of a cell.

Verma *et al.* disclose a recombinant, non-replicative, non-infectious retroviral transfer vector comprising: (1) a transgene encoding for luciferase or beta-galactosidase, and (2) retroviral regulatory signals, HIV-1 LTR and RRE. Verma *et al.* further disclose two additional vectors, a packaging construct comprising HIV Gag, Pol, Vif, Tat, Rev and Nef, and a pseudotyping MLV vector comprising HIV Env. See Figure 1. The Verma retroviral transfer vector does not comprise cPPT and CTS.

Charneau'94 discloses both the cis-acting cPPT and CTS in the HIV-1 upstream plus strand. Charneau'94 describes that cPPT is an important cis-acting sequence for initiating DNA transcription by priming DNA synthesis. See page 651, the sentence bridging the two columns, and right column, last paragraph. Charneau'94 further describes that HIV-1 CTS is essential for terminating DNA synthesis by displacing the completed DNA strand. See page 652, left column, 2nd paragraph. Charneau'94

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specifically discloses the nucleotide sequence of HIV-1 CTS. See page 654, Figure 2.

Charneau'94 does not disclose the nucleotide sequence of cPPT.

Charneau'92 discloses the nucleotide sequence of HIV-1 cPPT. See page 2815, Figure 1(a). Charneau'92 also discloses that cPPT is an important sequence for initiating DNA transcription. See page 2814, left column.

Neither Charneau'94 or Charneau'92 describes the formation of a DNA triplex. However, Giovannangeli discloses that a triplex-forming oligonucleotide, directed against the HIV-1 polypurine tract (PPT), can specifically recognize and bind its 15 bp target located on nuclear DNA involved in the intact supranucleosomal structure of chromatin (page 79, right column, middle paragraph). The targeted PPT sequence is located in the coding region of the *pol* gene but it belongs to a 500-bp fragment which has been shown to exhibit transcription-enhancing activity and to contain several transcription factor binding sites. Such a region associated with regulatory functions is generally distinguished from the bulk of chromatin by an increased accessibility of DNA to regulatory proteins and therefore appears also accessible to triplex-forming oligonucleotides (see the paragraph bridging page 81 and 82). Therefore, this PPT is the recited cPPT in the instant claims and provides the evidence that the cPPT is a target site for DNA triplex formation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Verma retroviral transfer vector so as to insert the initiation signal, cPPT, and the termination signal, CTS, from the upstream plus strand of HIV-1 genome, as taught by Charneau'92 and Charneau'94, upstream from the

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coding sequence of the transgene in the retroviral transfer vector taught by Verma *et al.*

The skilled artisan would have been motivated to do so to improve the transfer, integration and sustained long-term expression of the transgene inside a cell. There would have been a reasonable expectation of success, given the routine practice of molecular cloning in the art and the location of cPPT and CTS in the HIV-1 upstream plus strand for the initiation and termination of DNA synthesis, as taught by the two Charneau references. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. H./

Examiner, Art Unit 1648

06 February 2009

/Bruce Campell/

Supervisory Patent Examiner, Art Unit 1648